PRIMARY HEALTH CARE- QUALITY UPGRADATION THROUGH STANDARDISATION

SEMINAR REPORT

BANGALORE, APRIL 11 1996

CENTRE FOR POPULATION DYNAMICS
A DIVISION OF CENTRE FOR TECHNOLOGY DEVELOPMENT

&

BUREAU OF INDIAN STANDARDS

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Women In Development (WID)
Reproductive Health Programme

PRIMARY HEALTH CARE QUALITY UPGRADATION THROUGH STANDARDISATION

BANGALORE, APRIL 11 1996

A Seminar organised by

CENTRE FOR POPULATION DYNAMICS

A DIVISION OF CENTRE FOR TECHNOLOGY DEVELOPMENT

&

BUREAU OF INDIAN STANDARDS

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INTRODUCTION

The Centre for Technology Development (CTD) is a non-governmental registered society established in 1988 with USAID assistance. Among its mandates is the programme relating to Women in Development (WID) which has the primary focus on Education, Employment, Enterprise and Empowerment of women. Empowerment includes entitlement to health care not only for women but for children too, and the recognition of the reproductive rights of women. Under this mandate of WID, the CTD has established the Centre for Population Dynamics (CPD) as one its Divisions for evolving schemes and programmes relating to maternal and child health and reproductive health.

The CPD held consultations with expert groups to determine a framework for its activities, particularly in the context of the growing consensus after the recent Cairo Conference that family welfare, important as it is, should be implemented more appropriately as an integral part of programmes meant to improve reproductive health. Based on the conclusions of expert group discussions, and taking into account the findings of the National Family Health Survey for Karnataka, it was noted that the quality of health and family welfare services was a crucial determinant in their acceptability and utilisation.

The quality of health and family welfare services which impinge on reproductive health would, in turn, be dependent on their management. In this context, the establishment of standards relating to primary health care is very important. As a first step towards specifying and establishing such standards, a seminar was organised in collaboration with the Bureau of Indian Standards, Government of India, to consider the various parameters that would be relevant for this purpose. This report presents a record of the seminar on "Primary Health Care - Quality Upgradation Through Standardisation " and includes the papers that were presented.

The enthusiastic response and active involvement of the Bureau of Indian Standards is gladly acknowledged. The deliberations of the seminar were enhanced by the participation of experts and professionals. Their contribution to the discussions is also gladly acknowledged.

The report presents the conclusions of the seminar. It is proposed to carry forward this attempt at specification and establishment of standards at the level of primary health care. The CPD would take necessary further action in consultation with the health administrators and others concerned with the management of health services at the primary level.

REPORT OF THE SEMINAR ON PRIMARY HEALTH CARE - QUALITY UPGRADATION THROUGH STANDARDIZATION

A seminar on Primary Health Care - Quality Upgradation Through Standardization was held on Thursday, 11th April 1996 in the Conference Room, West End Hotel, Bangalore. The seminar was organized by the Centre for Population Dynamics (CPD), a Division of the Centre for Technology Development, Bangalore (CTD) and the Bureau of Indian Standards, Government of India, New Delhi (BIS).

The participants included health administrators, experts in evaluation and monitoring of health services, representatives of the BIS and other professionals involved in management of health services. The seminar was inaugurated by Mr. Gautam Basu IAS, Principal Secretary to the Government of Karnataka, Health and Family Welfare. The programme of the seminar and the list of participants are at Annexes I and II.

The genesis of the seminar was briefly indicated by Mr.P.C. Nayak, Director, CTD. The CTD, with the encouragement of the USAID its funding agency, has planned activities relating to women in development and one of the major focus areas is intended to be reproductive health. In this context, seminars on primary health care were conducted earlier which resulted in a recognition of the importance of the quality of such care being a major determinant of its acceptability, reach and efficacy. It was, therefore, considered useful to consider the issues relating to the standardization of key aspects of primary health care. For this purpose, the assistance of the BIS was sought, which they have readily extended. The seminar is part of the process of upgradation and effective management of primary health care.

Mr. Bhavnani, Director, Standards Promotion, BIS welcomed the participants. He emphasized the fact that quality improvement in primary health care was essential and a continuous process. Such quality improvement was possible by stipulation of adequate management practices. The need for a continuous internal audit of performance and quality management was emphasized.

Mr. Gautam Basu, in his inaugural remarks (Annex III), indicated that government accorded the highest priority to primary health care in view of its large clientele and vast reach but pointed out that the services could not be considered as adequate in terms of quality or availability. There were many reasons for this, including lack of staff, poor or inadequate training, lack of attention to detail, lack of intensive supervision and the like. Partial solutions to the adequacy of services could possibly be found by the induction into the health system of private doctors and other medical personnel to augment the services, but the quality of the services offered would be the key factor for ensuring their full utilization and acceptability. The provision of primary health care had as much to do with availability and adequacy as with its quality. The establishment and maintenance of quality services at the primary level would have to become part of the culture of health administration. This would need a careful review of its constituent elements, the monitoring of performance and the establishment of an in-built system of correction and supervision. The attention to detail was essential in this process. While the holding of this seminar was a good beginning, it was urged that the culture of quality in these services would have to be assiduously built up by training and the conduct of such seminars at district and other appropriate levels. With the State poised now for a considerable enhancement of health services at the primary level,

the need to consider issues relating to quality standards and developing standards for such services was evident.

Six papers were presented at the seminar (Annexes IV to IX). These were -

1. The objectives of the seminar - P.Padmanabha, Project Director, CPD;

   The utilization of primary health services is conditioned by perception of the client public regarding its availability, accessibility, adequacy and quality. Improving the quality of these services would include defining minimum standards of the services, identifying deficiencies or deviations from these minimum standards and adding essential services that may be missing. The ultimate test would be the increase in the use of these services by the public. Given the realities of finance, staff and the like, it may be necessary to determine priorities, in the beginning, in the services offered where quality standards are proposed to be stipulated and implemented.

2. Quality Management through ISO 9000 - J.K. Bhavanani, Director, Standards Promotion, BIS;

   Certification of quality does not refer to the best quality but what is, in a current situation, defined as the minimum essential. The important issue in both specification and maintenance of quality of service is to ensure that there is no reduction in the specified standards. The focus would have to be on customer satisfaction which would mean continuous attention to monitoring of the systems and procedures to ensure that quality is maintained. The interest and responsibility of top management would be important factors but the maintenance of

quality standards would presume the involvement of every staff member concerned. The focus would not be so much on inspection of performance as on prevention of fall in standards and their constant improvement.

3. Current Stipulations and Guidelines for Quality Achievement in Primary Health Care - G.V. Nagaraj, Additional Director, Health and Family Welfare, Government of Karnataka;

The emphasis on quality in the service sector is specially appropriate in the primary health care system. If one were to consider the family welfare service delivery system as an example, it would be evident that the unmet demand for such services noticed in recent surveys would have been very little had the quality of these services met the perceptions of the client public. The manuals for both management and training are available and could serve as inputs in training for the improvement of these services. If standards are specified and systems and procedures established for their institutionalization into the system of primary health care, the utilization of the latter would be considerably enhanced.

4. Standardization of Medical Devices and Hospital Planning - L.R. Singh, Director, Director, Medical Equipment and Hospital Planning Department, BIS;

In recent years there have been major advances in medical technology. The specification of quality standards for medical equipment and instruments is an important part of ensuring quality of medical care. Good manufacturing practices are part of the process of standardization since they ensure that the products meet the

customers requirements for quality, safety and performance. Various standards have already been established and need to be implemented to ensure a qualitative change. Equally important is the planning of health centres and hospitals at various area levels to cater to the needs of the public. The criteria for such planning would include adequacy of hospital care, technological adequacy, patient requirements, accessibility, record keeping and the like.

5. Quality Management for Health Care Services - A.K.Talwar, Director, Management and Systems Department, BIS;

The expansion of health care should be accompanied by the establishment of minimum quality standards of the services provided so as to make them more effective, acceptable and accountable to the consumer. Many quality standards have been stipulated for 30 bedded hospitals which, if implemented, would result in considerable improvement in the availability and quality of health care with regard to reliability, timeliness of care and its consistency in terms of quality. In the process of establishing quality standards for hospitals, the needs and expectations of the consumer should be central. The physical facilities and the qualitative aspects of health care would have to be considered together while planning a hospital.

6. Quality Upgradation in Primary Health Care - Sudha Xirasagar and Ashok Sahni, Indian Society of Health Administrators;

Health care has certain special characteristics which have to be taken into consideration while defining quality standards. These include intangible elements such as client-provider relationships and wide dispersal of services. Also, because it is usually free of cost to

the client, there is often no feedback to the supplier of the service of the client's perception of the service. The requirements of the primary health care services include the provision of essential health services universally with acceptable levels of quality. For this purpose there would have to be good record keeping, constant monitoring and supervision and an administrative culture that is prepared to learn from evaluation exercises with a view to maintaining quality levels at all times. Suitable parameters could be adopted to measure the efficacy of the primary health services such as coverage, trend in mortality and morbidity rates and the like.

Dr. Vikram Dutt of the Indian Society of Health Administrators made a special presentation on the information needs for establishing quality standards in primary health care. The need for a progressive adoption of standards was probably justified in view of the large and wide spread of both staff and services. An effective information system, with some degree of computerization, would be necessary. Such a system would, in fact, empower the doctors in the primary health care system to carry out micro-management better.

The discussion that followed the presentation of the papers took into consideration the difficulty in defining standards for various aspects of primary health care but it was recognized that the definition and adoption of such standards was an essential step in improvement of these services. The stipulation of such standards was the only way in which an acceptable minimum level of quality and adequacy of these services could be ensured.

However, the specification of standards of quality would have to be followed by intensive retraining of the health administrators at all levels so that

a "culture" of quality is built up within the hierarchy. The establishment of such a culture was not just a matter of training or reorientation. It would be dependent on the total commitment of the senior officers to quality and their constant involvement in the process of its maintenance. The character of supervision and monitoring would also have to undergo a qualitative change from being adversarial to cooperative.

Procedures for maintenance of buildings and equipment would have to be built into the system of quality assurance. This may require organizational changes, some of which are already under way. Since the quality of primary health care services is of vital interest to the public, it would be necessary to establish systems by which feedback of the public's perception of the quality of these services is available to the health administrators. One of the ways in which public involvement in maintenance of quality in this system could be established could be the setting up of Quality Control committees in each district made up of representatives from the health system, prominent nongovernment organizations and public figures. In this context, the active involvement of women members of the panchayati raj institutions should be encouraged.

The establishment of quality standards for various aspects of primary health care would need a clear conceptualization of the functions of the primary health centre and of the services it is supposed to provide. It should be possible to establish some degree of priority among these functions and services to enable standards being defined in a manner that would recognize field and administrative realities. However, such prioritization should not be to the neglect of the other normal responsibilities assigned to the primary health centre and its personnel.

It would be necessary to reiterate that standards reflect the minimum essential quality that could be expected as a matter of entitlement by the client public from the primary public health system. Such standards may vary over different regions and would certainly vary over time. Periodic review of the standards would obviously be necessary since, over time, the character and scale of the services would change.

The definition of standards and their specification would imply that an efficient system is established for evaluation of the performance of the PHCs and for monitoring the maintenance of the stipulated quality standards. For this purpose, specific parameters could be determined for the measurement of quality and for the continuous monitoring of the maintenance of the specified standards.

It was urged that the deliberations of this seminar be taken into consideration in such follow up action that may be contemplated.

Annex I

SCHEDULE

ENUE: Conference Room, Hotel West End, Bangalore *DATE : Thursday 11th April 1996*

Time	Topic	Speaker
09:30 - 10:10	Introductory Remarks	P.C.Nayak Director, CTD
	Welcome	J.K.Bhavnani Director, Stds Promotion
	Inaugural Address	Gautam Basu IAS Principal Secretary Health & FW, GOK
	Vote of Thanks	
10:10 - 10:30	The Objectives of the Seminar	P.Padmanabha Proj. Director, CPD
10:30 - 10:50	Quality Management through ISO 9000	J.K.Bhavnani
10:50 - 11:00	Coffee Break	
11:00 - 11:30	Current Stipulations & Guidelines for Quality Achievement in Primary Health Care	Dr. G.V.Nagaraj Addl. Dir, H& F.W
11:30 - 12:15	Standardisation of Medical Devices and Hospital Planning	L.R.Singh Director, MHD
12:15 - 13 :00	Quality Management for Health Care Services	A.K.Talwar Director, MSD
13:00 - 13:45	Lunch	
13:45 - 14:15	Quality Upgradation in Primary Health Care Curative, Preventive and Promotive including upgradation through Information Systems and Computerisation	Dr. Ashok Sahni Dr. Sudha Xirsagar Prof. Vikram Dutt Indian Society of Health Administrators
14:15 - 15:30	Open House Discussion	
15:30 - 15:45	Tea	
15 :45 - 17:00	Open House Discussion (contd) Conclusion	

Annex II

LIST OF PARTICIPANTS

1 . Mr. Gautam Basu
Principal Secretary, Health & Family Welfare, Govt. of Karnataka

2 . Dr. M.T. Hema Reddy
Director, Health & Family Welfare, Govt. of Karnataka

3 . Dr. G.V.Nagaraj
Addl. Director, Health & Family Welfare, Govt. of Karnataka

4 . Mr. V.S. Badri
Director, Population Centre, Govt. of Karnataka

5 . Dr. K. Thimmapayya
President, Family Planning Association of India, Bangalore.

6 . Smt. Subadra Venkatappa
Vice-President, Family Planning Association of India, Bangalore

7 . Ms. Kalpana Purushotaman
Research Associate & Training Officer,Essae Chandran Institute, Bangalore

8. Prof. P.Kesava Perumallu
SQC & OR Unit, Indian Statistical Institute, Bangalore

9 . Dr. Kishore Murthy
Founder Secy, Foundation for Research & Education Management, B'lore

10. Dr. Ashok Sahani
Hon. Exec Director, Indian Society of Health Administrators, Bangalore

11. Dr. Sudha Xirasagar
Public Health Specialist, Indian Society of Health Administrators, Bangalore

12. Dr. Vikram Dutt
Information Systems & Rehabilitation Systems Expert, ISHA, Bangalore

13. Dr. P.H.Rayappa
Head, PRC, Institute of Social and Economic Change

14. Mr. J.K.Bhavnani
Director, Stds Promotion, Bureau of Indian Standards, Delhi

15. Mr. L.R. Singh
Director, Medical Eqpmt. & Hosp. Planning, Bureau of Indian Stds, Delhi

16. Mr. A.K.Talwar
Director, Management & Systems, Bureau of Indian Standards, Delhi

17. Mr.V.Subramanyam
Director, Bureau of Indian Standards, Bangalore

18. Mr. B.R.Narayanappa
Joint Director, Bureau of Indian Standards, Bangalore

19. Mr.M.N.Murching
Director, Centre for Manufacturing Engineering,CMTI

20. Mr. P.V.B.R.K.Brahmam
Technology Consultant,Centre for Technology Development

21. Mr. K.P.Prabhakaran
HRD consultant,Centre for Technology Development

22 Dr. P.H.Reddy
Former Dir. Population Centre , Bangalore

23. Mr. P.C.Nayak
Director , Centre for Technology Development, Bangalore

24. Mr. G.Aswatnarayana
Advisor-Environment - Centre for Technology Devpt.

25. Dr. S.R. Sampath
Food and Nutrition Consultant, Centre for Technology Development

26. Mr. P.Padmanabha
Project Director, Centre for Population Dynamics

27. Mr. A.Prakash Rao
Senior Consulting Research Officer, Centre for Population Dynamics

28. Ms. Kripa Keshav
Centre for Population Dynamics

29. Ms. M.G.Padmavathi
Centre for Population Dynamics

Annex III

INAUGURAL ADDRESS BY MR. GAUTAM BASU IAS , PRINCIPAL SECRETARY, HEALTH AND FAMILY WELFARE, GOVERNMENT OF KARNATAKA

"I am happy to be associated with this seminar on quality upgradation of the Primary Health Care services.

The subject chosen for this seminar could not have been more relevant today. Since independence, India has been according the highest priority to primary health care services. It was rightly assumed that improvement of basic health care was the key to our success in reaching the "Health For All" goals. A vast network of primary health care services has been built up in this country over the decades. There have been massive fund allocations not only from the Govt. of India and the State Governments, but also from various external donor agencies. Karnataka has had four IPP type Area projects with the main objective of promoting and improving standards of primary health care. Within the primary health sector, top most priority has always been accorded to maternal and child health. An impressive range of Mother and Child health services, with considerable bed capacity has been built up.

Nevertheless time has now come to take a critical look at the functioning of the functioning of the entire primary health care network in the country. We find a very small percentage of the beds at the primary level are actually utilised. Mostly our PHCs and PHUs do not always measure up to the quality standards, people have a right to expect. Women find it difficult, if not impossible , to stay overnight at the rural hospital, which do not have adequate medical or para medical staff. Lady medical officers are becoming very hard to find, even though contract appointments are offered to the medical practitioners in their own districts. Lab technicians are not available in most hospitals and the laboratories themselves are not in good shape. The standards of maintenance of the utilities, cleanliness and sanitation waste disposal etc., are still quite poor. Therefore, obviously, the quality standards of the clinical or curative services offered by the primary health care set-up leave much to be desired.

The same is true, by and large, of the preventive and public health dimensions of the primary health care system. Our achievement in implementing the Family Welfare programme has not been inconsiderable; however, there has always been the criticism, often justified, of our obsession with targets and numbers at the expense of quality. It is only in recent years that the realisation has been dawning upon us that the target oriented approach is ultimately counter-productive. Even now in most states, the sterilisation programme reaches its peak only in the three months after December. The great pressure to make up for the lost ground obviously has an adverse effect on the quality of the services. There is therefore a need to place renewed emphasis on quality at every stage of this programme. The same would also be true of our drive to attain higher levels of success in spacing methods, especially insertion of IUD or oral pills.

We have had great success recently in implementing the Pulse Polio Programme. This was a massive effort, launched all over the country on a war - footing. While we Indians are perhaps quite good at taking on hand such massive crash programmes, we are somewhat wanting in the implementation of immunisation programmes in a day to day basis, taking good care of quality at every stage. Our lack of attention to quality is reflected in the gaps between the actual and reported coverage of immunisation of various kinds, in the disruption of the cold chain, and sometimes the failure to take basic precautions like sterilising the syringes, not using the same vial more than once etc. If only well-known quality norms are adhered to, taking recourse to massive crash programmes would perhaps not be necessary.

What exactly needs to be done is to inculcate a quality consciousness on, not only administrators, doctors, the para medical staff and the voluntary organisations , but also on the recipients of the primary health care services themselves. First of all, we need a strong IEC campaign to focus on quality. We need to spell out that quality is not a vague and abstract concept, but something that is realisable in a series of concrete steps. Once the public at large is made aware of the need for achieving high quality standards in health care, this awareness itself will generate a strong demand for a qualitative improvement in the services rendered, both by the public and the private sectors. Once the demand is expressed in the right quarters, those in charge of service delivery

will automatically be kept on their toes.

Fortunately 'quality' has now become the central concept in almost all organised human activities. In the wake of liberalisation and globalisation, Indian Industry is also fast becoming responsive to the need for quality improvement. We, in the health sector, can take a leaf out of Industry's book. Any industry which wants to be competitive, not only globally, but also nationally, has to acquire one of the certificates of the ISO 9000 series. Certification under ISO 9000 is not really about the final end-product of the concerned industry. This certification is about the correctness of the processes involved in making that product and also about a detailed documentation for these processes. What we need in the health sector is a concept or an approach of this kind. We should not think only in terms of the final stage at which a sterilisation operation is performed on the table or an IUD insertion is actually made, but of all the processes that go before and after this event. Once we get the processes right and also their documentation right, it would be very difficult for any link in the chain i.e. the village health worker, the ANM, the health supervisors, the medical officers, the surgeons and those in charge of supply of kits and drugs, to do anything wrong. If the sum total of all the process is right, then the entire activity will be performed at the highest quality level.

In terms of investment on health care, Karnataka is poised for a big leap forward. The State's own investment has been increasing every year. Recently we have been able to secure a number of externally aided projects, covering the entire range of primary and secondary health care. All this investment also gives us the responsibility to ensure the highest standards of quality in our health care services. In fact our success in making any fruitful use of these projects will depend largely on our ability to adhere to certain levels of quality in respect to each health services.

I thank the Centre for Population Dynamics and the Centre for Technology Development for organising this seminar. The findings and recommendations of the seminar will no doubt help us greatly in setting quality standards for ourselves in the health sector. I thank Mr. Padmanabha and Mr. P.C. Nayak for giving me this opportunity to be associated with this important seminar."

Annex IV

DEFINING QUALITY OF HEALTH SERVICES AT THE PRIMARY LEVEL

P.Padmanabha

The concern regarding the quality of health services at the level of the primary health centre is not of recent origin. There has been continuous study of the quality aspects of the family welfare programme, as a component of health activities, within government and of the management of general health systems by reputed research organizations. However, the results of the National Family Health Survey (NFHS) indicate that a hard look is now essential at the quality of these services, among other aspects.

The NFHS results indicate that 17 per cent of total fertility is accounted for by births to women - rather girls - of age 15 to 19. Also one in every eight births occurs within 18 months of the previous one. There are obvious implications, in this scenario, for the health of the mother and child, including the likelihood of survival. The NFHS also indicates that there is a strong desire among married women to either postpone their next child by at least two years or cease childbearing altogether. There is also a perceptible desire to space children. However, despite these strong desires, and with knowledge of family planning methods being near universal, only 41 per cent of married women use any method. The unmet demand for family planning services is nearly 20 per cent. Also, the infant mortality rates, including those of neo-natal mortality are disconcertingly high.

The results quoted are just a small, but important, part of the NFHS results but they raise questions of vital importance - why, with near universal knowledge of family planning, is the unmet need so high; why despite the wide network of Primary Health Centres are neo-natal and infant mortality rates high; why are more births occurring in homes than in hospitals, and the like. There are, of course, many reasons for this situation, but among them the main element would seem to be the lack of satisfaction of the clientele public of the

availability, accessibility, adequacy, and quality of the health services at the primary level. Of these elements, the enhancement of availability and accessibility would doubtless be conditioned by the quantum of annual budgetary allocations and on presence of supporting infrastructure. The other two, namely adequacy and quality would be dependent on the efficiency of internal management of the health delivery system at the primary level. We are here concerned with the latter issue.

The utilization of health services are strongly dependent on the adequacy and quality of these services. Improving the quality of service delivery at the PHC level would include defining minimum standards of quality of the services offered, identifying deficiency or deviations from this minimum standard and adding essential services that may be missing. The ultimate test would be the increase in use of the services by the public.

It is in this context that the specification of standards relating to primary health care becomes important. It would be desirable to define standards for specific components of the health services at this level. In fact, the Bureau of Indian Standards has already been engaged in specification of standards for health care services and standards have been set for some aspects. As part of this activity, it is considered most useful to consider the issue of quality upgradation of primary health care through standardization. The focus of this seminar would be mainly with the development of quality standards and their specification in health care at the primary level. While it would consider the quality aspects and standardization relating to medical devices, the focus would be on aspects relating to management of health care services. The methods and processes of upgradation of quality of primary health care via the ISO 9000 route would be discussed. The latter would include specification of procedures and management practices and principles for attainment and maintenance of the quality of these services.

The standards relating to primary health care that would have to be specified under the principles of ISO 9000 are not something esoteric or unrealistic [1]. In

[1] Some of the main general principles that govern ISO 9000 are presented in the Annex

essence, these would consist of the basic elements that should be identified to ensure that the services offered in the primary health care system meet, and preferably, exceed, the expectations of the beneficiaries of the system. To ensure that the system can be of universal applicability, the minimum requirements would have to be stipulated and specific activities and procedures to achieve the latter would have to be clearly documented. The specifications would have to include elements relating to organizational structures, responsibilities of the staff and standard procedures.

The specification of standards of primary health care on the ISO 9000 model would doubtless have to include aspects such as the appropriate type of building, minimum standards of equipment, staff structures and actual procedures. For example, the six elements that influence quality and determine the way the system provides services relating to family welfare programmes have been identified as (i) availability of choice of reliable methods (ii)adequacy of information given to clients (iii) technical competence of the staff, (iv) maintenance of cordial interpersonal relations, (v) mechanisms to encourage continuity and (vi) availability of an appropriate constellation of services[2] .

It would be possible to identify specific key aspects relating to primary health care that need standardization. In order to do so, one should be clear as to the objective of the services provided - what areas of public health are the services expected to impact upon, who are the beneficiaries, what are the main objectives of providing the services, and the like. Also, the quality of the services should represent the views of the recipients of the services and not that of the providers. The minimum standards of the latter would be set more by budgetary allocations and similar considerations rather than by adequacy of services of acceptable quality.

In the area of primary health, quality systems are probably of greater importance than in the case of other generic products. The components of quality in this area are more difficulty to define, quantify and monitor because the focal point

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2 Managing Quality of Care in Population Programs, ed. Anrudh K Jain, Kumarian Press, 1992; pages 10 - 11

of the system is people. The system has to take into account the perceptions of the customers of these services with regard to quality. A quality system for health would have to recognize that there are social processes involved, that human interactions are a crucial part of the administration of primary health care, and that motivation of both personnel and the beneficiaries would be involved. There would have to be planning for quality, continuous monitoring of quality and constant surveillance to maintain the stipulated standards of quality.

In establishing a system of quality standards in primary health one would have to consider, among other aspects, the following - (i) the purpose of the service and the beneficiaries to be served, (ii) its wide range of constituent elements which would include curative and preventive components, family welfare, those relating to maternal and child health, programmes of immunization and eradication, etc, (iii) the staffing pattern for ensuring adequate services in terms of availability and quality, (iv) the scale of equipment, (iv) the procedures adopted for providing or making available the services, (v) measurement of performance and monitoring procedures, and the like. A detailed review of the job responsibilities of the staff, including those of the Medical Officer, the Extension Officers, and the Health Assistants of various designations, would be necessary to determine the optimum scales of staff, equipment and supplies.

There is one aspect with regard to specification of quality standards at the level of primary health care. Given the realities of cost considerations, it may be necessary to determine some priorities in the types and content of the services sought to be provided. The latter would also be dependent on the availability of adequate supporting institutions such as the Community Health Centres and other health and medical facilities within accessible limits. Periodic reviews of the required standards would be necessary to expand facilities and services over time.

It is hoped that this seminar would provide some recommendations on the steps that could be taken to establish quality at the level of primary health care.

Annex

ISO 9000 - Introductory Notes.

ISO stands for the International Organization for Standardization which establishes voluntary standards for business, industry and services.

ISO 9000 is a written set of standards which stipulates the basic elements of a system that must be established to meet or even exceed the needs and expectations of the customer. ISO 9000 indicates the minimum requirements at a given point of time and is determined and designed within the organisation itself. In essence, it documents the specific activities and procedures that have to be followed to achieve the quality of the services (or product) expected. Basically, it is a system of procedures to ensure satisfaction of the client with the service that is being offered.

The objective of adopting an ISO 9000 quality system is to ensure that the service achieves and maintains the minimum standards expected by the client public. This quality system :

- plans the means by which the specified quality standards would be achieved,
- documents the procedures for this purpose,
- ensures that all personnel of the organization are aware of these standards and procedures, and
- monitors the maintenence of these standards.

Since standards are not static. the system would have to provide for a review of the standards themselves.

The adoption of an ISO 9000 quality system assumes total commitment of management and personnel to its implementation. The response and reactions of the client public would indicate whether the quality system is actually being followed. In other words, the organisation would have to demonstrate that the quality standards it has set for itself are being followed.

In the services sector the emphasis is on the satisfaction of the people. They are the focal point of a quality system such as in public health services. The perceptions of the public and their needs and expectations would determine the way the services are designed, managed and maintained. Human aspects would have to receive due recognition in the stipulation of quality standards. These would include the inter - personal relationships between the provider of the service and its beneficiary, the enhancement of the motivations of the personnel to perform to specified standards, constant attention to improvement of skills and the need to maintain the image of quality at all times. In particular, in services relating to public health timeliness would be an important constituent element in determining quality.

QUALITY MANAGEMENT THROUGH ISO 9000

J.K.Bhavnani

1. Introduction

1.1 Every company wants to be successful in business. The aim of business is to bring prosperity to individuals, family and the country. The customer is the purpose of your being in business, profit is simply the reward which must follow if you keep your customers happy. The business could be small, medium or large. This business activity could be trading, distributorship, selling, manufacturing or service.

1.2 Until recently, companies enjoyed a protected market because of restrictive economic policies of our government, and the customer had no choice but to buy whatever was available. Buying power was also limited.

1.3 Economic scenarios have changed due to breaking up of USSR, unification of Germany and emergence of European Common Market Community, Government of India has also decided to benefit from the change by revising the economic policies. The business restrictions are removed so that Indian businessmen can also prosper by benefiting to sell anywhere in the world. On the other hand, it has invited outside businessmen to come, invest and set up business in India.

1.4 Apparently the business scenario is changing from sellers market to buyers market and success of company's share depends primarily on the quality of their products and services that satisfy the customers need in all respects including cost. Tremendous competition from companies outside India is expected. Therefore Indian companies need to be more aware of the global quality assurance requirements.

1.5 Due to liberalisation of economy, there is an upsurge of activity in the Indian industry to upgrade quality to meet the global market requirements. It has recognised quality as a passport for entry into new markets and necessary for long term survival in competitive market place.

1.6 In pursuit of excellence, quality has taken a tangible form with advent of ISO 9000 series of standards . These standards have become the subject of intense focus through out the world. They are recognised internationally as a benchmark for measuring quality . ISO 9000 built round the concept of quality provides measure of organisation's ability to consistently deliver a product of service that meets the requirements of its customers.

2. Government initiative to promote quality

2.1 With the progressive development of Indian economy towards a free market oriented economy, aspects like productivity, efficiency, quality and competitiveness have emerged on the fore front. These received impetus from national policies to increase exports and strengthen the economy. The Import - Export policy (1992-97) announced by the Government of India set the ball rolling. Recognising that quality upgradation through the medium of standards and certification systems has an important role to play , the policy focuses on building international competitiveness in goods and services. Quality has taken the prime place in the policy to win over international customers' confidence by providing goods and services of consistent quality. The Government initiative to support and promote the quality programmes include :

a) Quality Awareness Campaign - For creating awareness, the prime minister of India launched a quality campaign in 1992. The Government has decided to assist the Trade and Industry Association for conducting nation-wide programmes on quality awareness particularly application of ISO 9000.

b) Rewards and benefits - The Government has introduced a scheme to recognise and reward manufacturers who have acquired ISO 9000

or any other equivalent recognised international certification of quality systems.

c) Test Houses - The Government will assist modernisation and upgradation of test houses and laboratories to bring them up to the international standards so that certificates issued by them are recognised within the country and abroad. Three sectors, namely food processing, automobile components and domestic electrical appliances have been identified for upgradation under the Indo-European Union (EU) Co-operation Programme.

3. Quality Concepts

3.1 Principal factor in the performance of an organisation is the quality of its products and services. Most organisations - industrial, commercial, or government - produce a product or service intended to satisfy a users need or requirements. Such requirements are often incorporated in "specifications". However, technical specifications in themselves guarantee that a customer requirements will be consistently met if there happens to be no deficiency in the specifications or in the organisational system to design and produce the product or service. This has led to the development of quality system standard and guidelines that complement relevant product or service requirements given in the technical specifications.

3.2 Definition of Quality :

Oxford Dictionary - "Degree of excellence"

JURAN - "Fitness for purpose"

" Conformance with Requirement"

After careful consideration of the various definitions existing, ISO has brought out the following definition of quality :

" The totality of features or characteristics of a product or service that bears on its ability to satisfy the stated and implied needs ."

3.3. Key concepts - There are three key concepts of quality :

a) Production Quality is management responsibility- management must accept the responsibility for quality of the products developed in the organisation.

b) Producers must be involved in quality control- All workers connected with developing a product should be actively involved for the establishment of their own standards and procedures and also adhering to them.

c) Quality is a journey, not a destination - Quality is a continuous improvement process.

4. Quality System Standards

4.1 Series of standards by which an organisation's quality management system can be installed, operated and evaluated both in-house and independently by third parties. ISO 9000 built around the concept of quality provides measure of an organisation's ability to consistently deliver a product or service that meets the requirements of its customers.

4.2 India has taken initiative in implementing ISO 9000 in Indian industries. As a first step, it adopted these standards in toto and brought them out as IS/ISO 9000 series of Indian standards. The series has expanded and more standards have been associated with the series to be called as ISO 9000 family of standards. The inter-relation of standards is given in Fig 1.

5. Steps towards implementation of ISO 9000

5.1 The best strategy for an organisation to pursue when embarking on the road to ISO 9000 implementation is to adopt a simple model. It is better to design a quality assurance model from bottom up to ensure that what is done is

indeed what is documented. In any organisation, some of the documentation required by ISO 9000 standards are already in place. These must be taken cognizance of. The main steps involved in implementation of ISO 9000 in an industry are :

5.1.1 Management Commitment - The quality starts with the top management. Therefore, it is imperative that the top management should have an awareness of the ISO 9000 quality management system standards; that is, what is ISO 9000 and why is it important for the business. The management should then define quality policy and quality objectives and commit to the introduction of an efficient and effective quality management system. The next task is to transmit the management commitment and enthusiasm to the entire work force. It must be ensured that everybody in the organisation understands quality policy. But before a decision is taken to pursue certification, the management needs to address the issues such as how quality management system will help streamlining processes; is certification necessary for future business; What are the short term and long term benefits and how much will certification and subsequent surveillance audits cost.

5.1.1.1 It is the management's responsibility to lead the quality effort and to allocate resources. Therefore, it is imperative to obtain management's commitment and involvement right from the start of the project.

5.1.2 Setting up of a steering group - Having evolved the policy and decided to pursue quality management system, a small strong core team should be formed to spearhead the ISO 9000 project. It should become the focal point for all issues relating to the standards. This team shouid initially receive training in ISO 9000 requirements and then educate all the employees in the organisation to the extent necessary. This team becomes communication link between progress in the ISO 9000 implementation and the management.

5.1.3 Review existing procedures - When an organisation starts on the road to ISO 9000 , it rarely does so from ground zero. In most cases, the organisation in question will have a quality system in place. The core team therefore, compares the organisation's current procedures and practices with the requirements of ISO 9000 standards. The team then identifies gaps that

appear (this process is often called a gap analysis) and starts the process of closing them. This process should identify the responsibilities for closing those gaps and evolve a time table for completion. This review gives an insight into the present systems and procedures and their adequacy or inadequacy to meet ISO requirements.

5.1.4 Documentation - The most important of entire ISO 9000 implementation is documenting the system. The core team should compile a quality manual to address all pertinent elements of ISO 9000 standards . The normal level of documentation fall in the following categories :

a) Quality system manual;

b) Operating procedures;

c) Work instructions; and

d) Forms/ formats

5.1.5 Awareness and training programmes - Training in ISO 9000 should begin with the management staff. The management representative (a person appointed with defined responsibilities to ensure that quality system is implemented and maintained) should provide the necessary training. The Standard mandates the supplier (organisation seeking certification) to have a quality policy and objectives, understand them and be deployed through out the organisation. The policy must be indoctrinated into the people. They must understand what it is and they must be aware of its implications with respect to their job. A training programme should then be established for all employees that impacts upon the quality of a product / service.

5.1.6 Internal Audit - The standards require the organisation to carry out planned and documented internal quality system audits. The purpose of the audit is to evaluate the degree of implementation and to ensure effectiveness of the quality system. Internal quality audit is an effective instrument that identifies weak areas that need improvements. Internal auditors should, therefore, be trained and should be able to recognise system breakdowns and recommend corrective actions. Also, they should be independent of the functions they are assigned to audit.

5.1.7 Pre-assessment by an external agency - When the organisation feels that its quality system is in place, implemented and functioning according to standard and deficiencies are no longer visible, it is the time for the organisation to put in application for third party certification. Before taking this action it is advisable to organise pre-assessment / trial assessment from industry association or certifying agency. The objective is to determine if the system is ready for final certification audit.

5.1.8 Final certification audit - A formal application along with the quality manual is filed with the certification agency. The third party certification agency conducts adequacy audit of the organisation's quality manual and compares that against the pertinent ISO 9000 standard. Once the quality manual confirms to the standard, a site visit is scheduled where the auditors from certification agency conduct rigorous assessment of the entire quality system.

6. Quality System Certification Scheme

6.1 In keeping with the changing international business scene and bold measure taken by Government of India in the form of new trade and industrial policy to face international competition, the Bureau of Indian Standards launched Quality Systems Certification Scheme in 1991. The BIS is the national agency authorised under the Bureau of Indian Standards Act 1986 and the rules and regulations framed thereunder to operate quality system certification in India. It has international accredition from RAAD VOOR DECERTIFICATE (RvC), Netherlands which demonstrates its capability and credibility to operate quality system certification.

6.2 The main requirement - Standards against which an organisation can be certified are :

a) IS / ISO 9001 - Model for quality assurance in design, development, production, installation and servicing.

b) IS / ISO 9002 - Model for quality assurance in production, installation and servicing.

c) IS / ISO 9003 - Model for quality assurance in final inspection and testing.

6.2.1 The three models of quality management systems covered in the above standards establish procedures for quality assurance to the customers at various stages through the life cycle of a contract. Compliance with these standards require that a system be in place according to the requirements of the model chosen in consonance with the organisation's operations. The other standards in the family provide support for installation of the quality system to meet the requirements of the three models.

6.3 Procedure for IS/ ISO 9000 certification - The organisation desirous of obtaining a certificate under Quality Systems Certification Scheme has to apply on the prescribed form. On receipt of application, adequacy audit of the quality manual is carried out in accordance with the standards and modifications if any, are conveyed to the organisation. After this, a preliminary visit is organised to the firm for evaluation of its size, nature of operation, type of specialisation required, mandays needed for audit, readiness of organisation for final assessment and preparation of audit programme. The assessment of quality system is done by a team of qualified auditors. Procedure has been explained in a diagram (see fig. 2)

6. 4 Third party certification provides proof of adherence of ISO quality assurance system to an exporting company and acts as an "International Visa" of quality. By offering a coherent globally recognised alternative to multiple national assessments of quality, ISO 9000 thus contributes to the development of open markets.

6.5 Surveillance - After the grant of license, surveillance visits are made by the certification body to ensure that the licensee's quality system is being effectively maintained. The surveillance audit is very important to keep those who manage quality management system on the alert. It evaluates PDCA Cycle - Plan, Do, Check and Act .

7. Conclusion

7.1 ISO 9000 Certification provides a competitive edge in the world market. If an organisation is to attain and sustain the goals of high quality in its goods and services, implementation of ISO 9000 will go a long way in realising such goals. The success of implementing ISO 9000 largely depends on development of team spirit throughout the company for continuous improvement in the quality of goods and services offered to customers both internal and external.

7.2 In an increasing competitive international market third party quality assessment has become a prerequisite for doing business. In Europe purchase organisations place great reliance upon the ability of their suppliers to demonstrate that they are operating effective quality upgradation system which meet the requirements laid down in ISO 9000 series of standards. To the supplier, it is invaluable to be able to provide objective evidence that he operates an effective quality support system which has been examined and approved by an independent and well qualified third party certification body.

FIG - 1

SELECTION AND USE OF QUALITY SYSTEMS STANDARDS (ISO 9000)

ISO 9000.1 Guideline for Selection & Use
ISO 9000.2 Generic guidelines for application of ISO 9001, 9002 & 9003
ISO 9000.3 Guidelines for application to software
ISO 9000.4 Guide to dependability programme management

GUIDELINES FOR AUDITING QUALITY SYSTEM (ISO 10011)

ISO 10011.1 Auditing
ISO 10011.2 Qualification criteria for quality system auditors
ISO 1001.3 Management of audit programme

QUALITY ASSURANCE MODELS

ISO 9001 Quality assurance in design, development, production, installation and servicing
ISO 9002 Quality assurance in production, installation and servicing
ISO 9003 Quality assurance in final inspection and test

QUALITY MANAGEMENT AND QUALITY SYSTEMS STANDARDS (ISO 9004)

ISO 9004.1 Guidelines (General)
ISO 9004.2 Guidelines for services
ISO 9004.3 Guidelines for process materials
ISO 9004.4 Guidelines for quality improvement
ISO 9004.6 Guidelines to quality in project management

SUPPORTING TECHNOLOGIES

ISO 10005 Guidelines for quality plans
ISO 10007 Guidelines for configuration management
ISO 10012 Quality assurance requirement for measuring equipment
ISO 10012.1 Metrological confirmation system for measuring equipment
ISO 10012.2 Control of measuring process
ISO 10013 Guidelines for developing quality manual
ISO 10014 Economic effect of total quality management

FIG. 1 STRUCTURE AND INTER RELATIONSHIP AMONG ISO 9000 FAMILY OF STANDARDS

FIG - 2

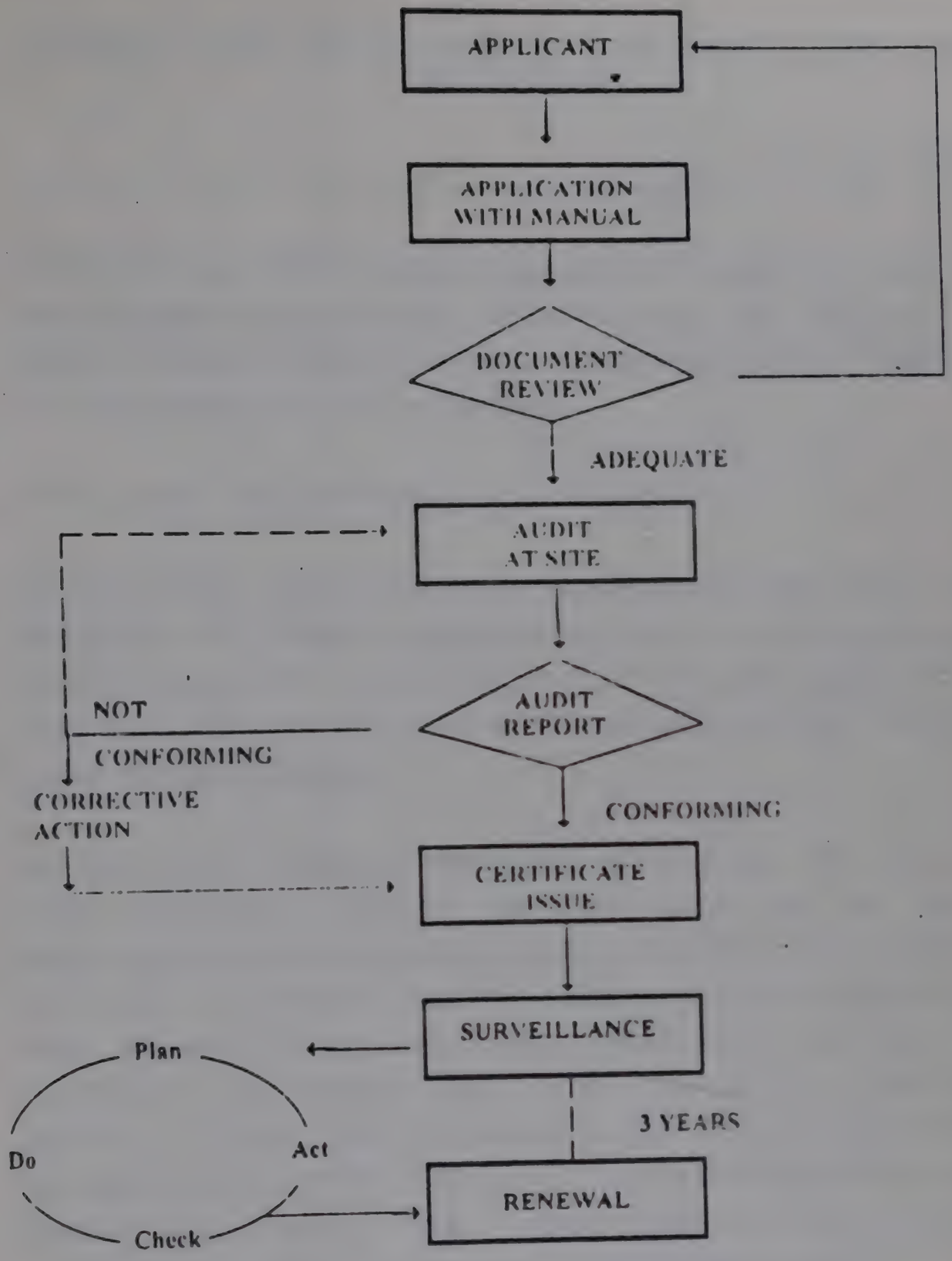

Fig. 2 Certification Flow Chart

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Annex VI

TARGET FREE APPROACH (TFA) IN FAMILY WELFARE PROGRAMME

Dr. G.V.Nagaraj

For over 30 years Family Welfare Programme was known for its rigid, target based approach in contraceptives. The performance was measured by the reported numbers of acceptors of the four contraceptive methods- Sterilisation, Intra-uterine device, oral pills and condoms.

This was widely criticised for being a coercive approach.

The main recommendations of the World Bank Report or India's Family Welfare Programme (FWP) is that the programme is to be re-oriented expeditiously to a Reproductive and Child Health approach (RCH). The main objective of which would be to meet individual client health and family planning needs and to provide high quality services.

The 1994 Cairo International Conference on Population and Development (ICPD) formalised a growing international consensus that improving reproductive health including family planning is essential to human welfare and development. The principle goal of a reproductive health programme is to reduce unwanted fertility safety thereby responding to the needs of the individuals for high quality health services as well as to demographic objectives. A growing body of evidence and the Cairo consensus suggest "Numerical Method Specific Contraceptive Target and Monetary Incentives" for providers to be replaced by a broader system of programme performance goals and measures focussed on a range of reproductive health services.

The World Bank Report concludes that the current contraceptive "Target and incentive" system gives a demographic planning emphasis to family welfare programme (FWP) which is antithetical to the reproductive and child health client centred approach advocated in the GOI - ICPD country statement for the

Cairo Conference.

In particular, emphasis on numeric targets is a major reason for the lack of attention to the individual client needs and is detrimental to the quality of services provided.

The report recommends that the targets be replaced by a broad set of performance goals

> "Government's goals for family planning should be defined in terms of unmet needs for information and services. Demographic goals should not be imposed on family planning providers in the form of targets or quotas for the recruitment of clients." - WORLD BANK - 1995.

The Government of India has abolished condom targets effective from April 1st 1995 and invited all the States to eliminate Contraceptive targets in one district beginning in April 1995. These districts are expected to provide an excellent opportunity to reproductive and child health to test the feasibility of providing an essential reproductive and child health package to assess its cost and to evaluate whether it enhances couple's ability to avoid unwanted pregnancies safety in comparison to the target approach.

During 1995-96, Government of India decided to experiment with replacement of contraceptive targets in the States of Kerala, Tamil Nadu, Union Territory of Chandigarh and 18 Districts in major States.

Accordingly, Mandya District has been identified and selected as the first district to implement the TFA from April 1995 in Karnataka State.

A set of performance goals and indicators has been worked out that would replace the earlier targets and emphasise quality issues in the district both in Family Planning methods and Mother and Child Health programmes (Study of monitoring format)

The Target free approach is being extended throughout the country in the year 1996-97. During the Family Welfare Secretaries Meeting held in New Delhi on

1st and 2nd of February 1996, Karnataka State has agreed to add 9(nine) more districts to implement T.F.A. They are: Kolar, Tumkur, Chitradurga, Shimoga, Mysore, Dakshina Kannada, Kodagu, Hassan and Chikkamagalur. In the remaining 10 (ten) districts, the programme activities will be quantified in terms of expected level of achievement. Further, the programme performance goals and quality indicators will be monitored along with other TFA. districts.

A strategy is suggested for a "demand driven" and "quality conscious" Family Planning Programme which will be implemented on the basis of T.F.A. The following steps will have to be taken up immediately.

a) Sensitisation of the District Health & Family Welfare Officers, Medical Officers and Para Medicals on specific aspects of quality improvement.

b) Formulation of Annual Family Welfare Plan. The plan will comprise Family Welfare needs of the area, programme to be implemented to motivate potential acceptors, resources required such as medicines, contraceptives, mobility. This plan will be the basis for monitoring the work of the PHC. This would also mean that the PHC would set its objective relevant to the population of the area. In this manner, the target free approach will originate from the PHC level.

Proforma for monitoring monthly District-wise F.W. Indicators
(For Districts with no target)

State _____ District _____ Month _____ 199

PART(A) : Family Planning Programme

A.1 Sterilisations

	During the month			Cumulative since April		
	Tubectomy	Vasectomy	Total	Tubectomy	Vasectomy	Total
(1)	(2)	(3)	(4) (2+3)	(5)	(6)	(7) (5+6)
i)With 2 or less children	-	-	-	-	-	-
ii)With 3 children	-	-	-	-	-	-
iii)With more than 3 children	-	-	-	-	-	-
Total (i+ii+iii)	-	-	-	-	-	-

A.2 IUDs

	During the month	Cumulative since April
Age of acceptors		
i) less than 30	-	-
ii)Age of acceptors more than 30	-	-
TOTAL (i+ii)	-	-

A.3 D.P. Users

	During the month			Cumulative since April
Age of acceptors	Continuing	New	Total	
i) Less than 30	-	-	-	-
ii)More than 30	-	-	-	-
Total (i+ii)	-	-	-	-

A.4 C.C. Users

	During the month			Cumulative since April
Age of acceptors (Age of wife)	Continuing	New	Total	
i) Less than 30	-	-	-	-
ii)More than 30	-	-	-	-
Total (i+ii)	-	-	-	-

PART (B) IMMUNISATION PROGRAMME

B.1 No. of Immunisation Sessions: a) Planned _____
b) Actually held _____

B.2 ANTE - NATAL CARE CASES

	For the month	Cumulative since April	% of estimated Annual No. of deliveries
(a) Institutional deliveries			
(b) Domicilliary deliveries			
Total deliveries (a+b)			
(c) Domicilliary deliveries conducted by			
(i) HW (F)/LHV			
(ii) Trained Dais			
(iii) Others			

B.3 MTP

(i) Institutions providing MTP services		
(ii) MTPs done		
(iii) Women treated for complications following unsafe abortions		
(iv) Institutions providing emergency obstetric care		

B.4 Diseases

	For the month		Cumulative Since April	
	Cases	Deaths	Cases	Deaths
(i) Tetanus Neonatorum				
(ii) Poliomyelitis (Acute)				

	For the month	Cumulative since April	% of estimated Annual No. of cases
(iii) Pneumonia cases under 5 years			
a) identified			
b) treated			
(iv) Diarrhoel diseases and ARI			
a) No. of IEC sessions planned			
b) No. of IEC sessions actually held			

Date: _____

_____
Signature of Distt. Officer.

Annex VII

STANDARDISATION OF MEDICAL DEVICES AND HOSPITAL PLANNING

L.R.Singh

Medical devices have played and will continue to play an important role in the performance of health care services world over. In the past decades, we have witnessed major advances in the field of health care.These advances have furnished new methods for saving lives and resulted in the development of many new and critical life saving medical devices. Thousands of new and innovative medical devices enter the health care system every year.

The need for standardisation of medical devices was felt since a very long time.The Bureau of Indian Standards (the erstwhile ISI), the National Standards Organisation , has been involved in the formulation of Indian Standards in the health care technology since 1964, when the Consumer Products and Medical Instruments Division Council was established. It has played a significant role in preparing standards in the field of Health Care Technology and especially that of medical devices such as surgical instruments and medical equipment (Anaesthetic, respiratory equipments, transfusion and infusion equipment, implants for surgery, radiographic and diagnostic equipment, opthalmic, thoracic and cardiovascular surgery equipment), dentistry, hospital equipment, aids for disabled for handicapped and electromedical equipment.

The medical profession today employs more than 15000 different instruments, equipment and apparatus and a variety of materials. All these have been developed over many years to cater to the needs of individual surgeons and physicians and in many cases depending on his achievement and standing, the equipment became associated with the surgeon's or physician's name.

About 50 technical committees are working for the preparation of Indian Standards in the medical field. The standards are evolved by a consensus of

opinion of all interested parties, namely manufacturers, users, professional associations, technologists, scientists and others concerned with the specialised field. The formulation of a standard is a specialised skill of pooling all aspects of technical know-how. The Bureau of Indian Standards (BIS) is the national agency created for this purpose and brings about an acceptable agreement in the form of a standard.

Definition of Medical Device as per IS 12572(part 1) / ISO 10993-1

Any instrument, apparatus, appliance, material or other article including software, whether used alone or in combination intended by the manufacturer to be used for human beings solely or principally for the purpose of :

Diagnosis, prevention, monitoring, treatment, or alleviation of diseases, injury or handicap.

Investigation, replacement or modification of the anatomy or a physical process

Control of conception

and which does not achieve its principal intended action in or on human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Human health by its very essence, concerns one and all and it is a field where a rapid technical progress taking place in the methods of treating people must be channelled by harmonising the national standards with the international standards to be fully effective. An exchange of information and opinions by experts in this field is required to establish and maintain the necessary guidelines and standards for the manufacturing and utilisation of medical devices.

Good quality medical devices save lives and it is important that as many centres within the country as possible be equipped with the requisite equipment. Indian standards by making parts interchangeable and enabling the manufacturers to know the quality and specific characteristics they should aim to produce, are significant tools in making the devices marketable throughout the country and the world, function correctly and priced to be within reach of

most modest budgets.

Most standards in the field are new obviously but, there are 'sterling standards' that stand the test of time after periodic revision. Recently for instance, Thoracic and Cardiovascular Surgery Instruments Sectional Committee, MHD 6 has brought out IS 13924 :1994 which is a dual number adoption of ISO 5840:1989.

The areas with which this standard is primarily concerned are those that facilitate quality assurance. aid the surgeon in his choice of heart valve substitute and ensure that the device will be presented in a convenient form at the operating table.

Good Manufacturing Practices (GMP) is a recent concept in the area of quality assurance. It represents the sum total of these activities necessary to ensure that the product meet the customers requirement for quality, safety and performance. The basic principles are :

1. An integrated system of manufacture and quality assurance
2. Separate management responsibilities for both production and quality assurance
3. Suitability of premises, equipment and materials
4. Trained personnel
5. Document procedures for manufacture and quality assurance
6. Appropriate batch and product records
7. Adequate transport and storage facilities
8. A recall system
9. A system for auditing the operation of GMP.

GMP guidelines are complementary to such specification guides or codes which detail specific requirements for specific products such as National Standards or Company Standards.

With the national commitment to provide health for all by the year 2000 A.D, the requirements of medical equipment in India has to be viewed from the following angles:

a) Equipment necessary for Primary Health Care should be made

available to the rural hospitals and primary health centres, and in some cases , to the district level hospitals.

b) Sophisticated equipment to be used in the institutes at the regional level / state capitals / teaching institutes.

c) Special equipment for institutes of national level / privately funded hospitals and facilities etc.,

The cost of equipping all the hospitals is going to be enormous if everything is to be imported. The country has established a sufficiently strong infrastructure for meeting the general requirements of diagnostic and therapeutic equipment for a medium sized hospital. However, in many cases, equipment need to be properly evaluated and appropriate engineering designs require to be provided. Through suitable inputs, the level of such equipment can be upgraded to that of international standards. Without development and upgradation of existing equipment it is impossible to provide effective coverage on medicare to the large and heterogeneous population. It is only through a high technology base, design and development, competence and production capability in electronic medical equipment that the country could be provided with the latest medicare facility at all levels.

Biological Safety

Biological safety in medical devices is of paramount importance from the health and safety point of view. Accordingly Indian Standards for guidance on Biological evaluation of medical devices have been evolved under IS 12572 (Pt 1 to 14). These standards specify the tests necessary for devices that are implanted in or used on the body as well as the tests used to ensure biological safety and non-toxicity from a wide range of potential hazards including those with both short term and long term effects. They apply to medical equipment , surgical equipment and instruments, dental materials , implants and for selection of other medical devices. It is hoped that Biological evaluation of medical devices will, by painstakingly gathering the evidence from tests of the reliability of methods, reduce the need for individual national testing of devices confirming to the relevant standards.

Implementation of Indian standards and Certification Marking

Compliance of Indian standards in respect of medical instruments / equipment is by and large voluntary at present. So far the organisations such as DGAFMS, DGI, RDSO and DGS &D have adopted most of the Indian standards for surgical and medical equipment in their purchase program. Recently Govt. of India has taken a decision to bring the Diagnostic Medical X-ray equipment under mandatory BIS Certification for mechanical and electrical safety requirements as per IS 7620 (part 1): 1986 and only those X-ray equipment which confirms to IS 7620(part 1):1986, will be further tested by Atomic Energy Regulatory Board for radiation safety as per IS 7620(part 3):1991 which is a statutory requirement for such equipment.

At present about 36 Indian Standards belonging to medical devices and material are covered under BIS Certification Marks Scheme, for which 79 licences to use Standard Mark have been granted. Important medical devices under certification are :
Clinical Thermometers, Sterilisers, Hypodermic syringes and needles, Sphygmomanometers, M.T.P and general purpose Suction apparatus, Surgical dressings, Dental materials, Surgical B.P blades, Dental chairs, etc.,

There are however, certain practical problems due to which the surgical instrument manufacturers are not coming forward to cover their products under the existing framework of BIS certification marking scheme. One of these reasons being the small quantum of production in case of most of the manufacturers but with a large number of sizes / variety of surgical instruments / equipment involved. Efforts are on to bring about a viable solution to this typical problem in medical device industry.

The Drugs Controller of India has in the recent years declare the following medical devices as "Drugs" under the Drugs & Cosmetic Rules, 1940, as per which their conformity with the relevant Indian Standards has been made mandatory:

Transfusion sets for single use ; IS 9824 : 1981
Infusion sets for single use ; IS12655 (Pt 4) : 1988

Sterile Hypodermic syringes for single use ;IS 10258 : 1995
Sterile Hypodermic needles for single use;IS 10654 : 1991
Copper T (200B) ; IS 12418 (Pt 4) : 1991
Tubal ring ;IS 13009 : 1990

Indian Standards have also been aligned with the statutory rules a regulations framed by the authorities for safe and accurate performance medical devices. For example, clinical thermometers have to comply with t provisions of Weights & Measures Act. 1960.

There exists an urgent need for a speedier implementation of Indian Standar in the medical field so as to bring qualitative as well as quantitative changes augmenting the medical facilities to benefit the masses in the country a achieve the goal of "Health for all by 2000 A.D.".

Hospital Planning

The task of designing and planning of a hospital is an important factor whi matters in the quality of health care. Work of formulation of standards hospital planning has been taken up by the Bureau of Indian Standards 1986 and this subject was identified as a thrust area by the Bureau.

The factors influencing the planning of a modern Hospital are :

Hospital care

Hospital care has an important role to play in delivering quality health care. Th pattern of Hospital care has undergone radical changes during recent year There has been an increase in surgical load due to introduction of orga transplant, open heart surgery, etc.,

Technological Innovation

Technological innovations find their way in medical care from many source like nuclear medicine and solid state electronics in the form of ultra sound, C Scan and NMR. The designer of hospitals has to pay special attention accommodate these specialities in planning.

Patient Education

By creating patient education facilities, the hospitals could assume the role of health education centres and become much more involved in preventive, promotive and environmental medicine. The space marked for OPDs can be used as a class room in the evenings.

Computerisation

Storage space for record and paper processing can be reduced by use of computers. Records needing long retention can be miniaturised and stored.

Distance from Urban area

Creating convalescent home as self - care area with the hospital away from urban area where land may be cheap.

Commercialisation

Emergence of corporate hospitals with group practice is a new factor. Practitioners like to have strong up-to-date diagnostic as well as five star in-patient facilities for their clients, while investors want more profit. With the boom in money market, more industrialists and Non-Resident Indians may like to invest in corporate hospitals.

Hospital Building

Among the various types of buildings, hospital buildings need to fulfil certain additional requirements because of specialised features of such buildings from comfort and operational point of view, coupled with the need for close coordination and integration of hospitals facilities. The National Building Code of India, 1983 (NBC) published by BIS, classifies the hospitals under the Group C Institutional Buildings as distinguished from other kinds of buildings, based on occupancy type. As per the NBC, the Institutional Buildings have been further grouped as :

Subdivision C-1 Hospitals and Sanitoria

Subdivision C-2 Custodial Institutions

Subdivision C-3 Panel and Mental Institutions

The requisite guidance and requirements for hospital buildings pertaining to Administration, development control rules, Fire protection, building materials, structural design, construction practices and safety, building / plumbing services for these sub-groups have been detailed in NBC.

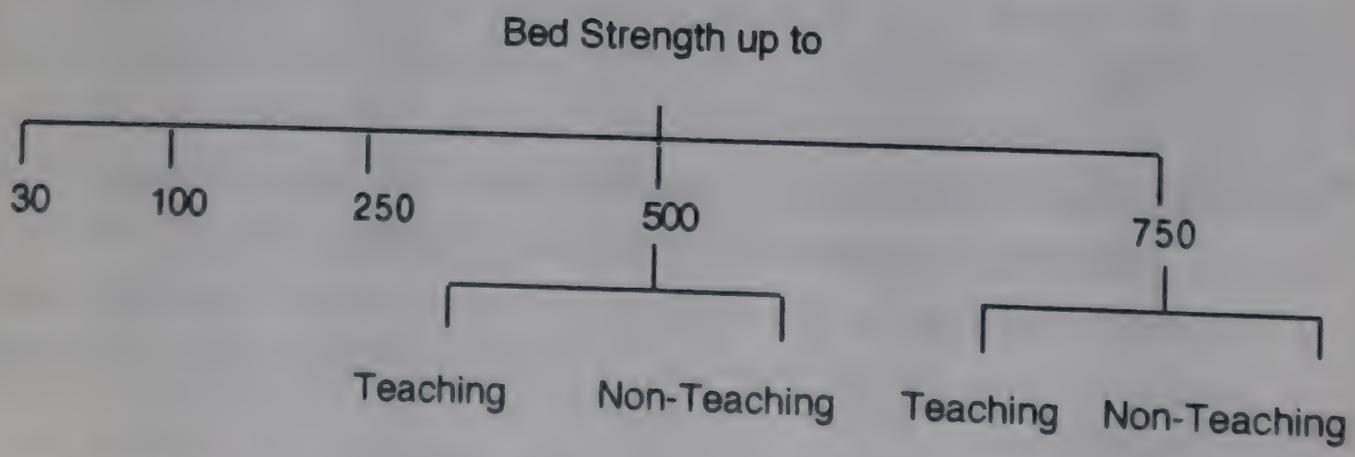
In addition to NBC, IS 10905 "Recommendation for basic requirements for general hospital buildings" has been brought out by BIS in three parts as under:

Part 1 Administration and hospital services department buildings
Part 2 Medical services department buildings
Part 3 Engineering services department buildings

These standards cover area requirements, site planning and flow areas in different units of various categories of hospitals, and provide guidelines on spatial, functional and environmental requirements of hospital buildings.

Norms for Planning Medical and Health Care Facilities

Hospitals cater to the need of various sectors of population at village, district and urban levels. BIS in view of the need for the classification of the hospitals catering to the different segments of population has brought out IS 12377:1988 " Classification and matrix for various categories of hospitals" , categorising hospitals on the basis of bed strength as follows :



The standard also gives a matrix with functional classification for various categories of hospitals.

Planning of hospitals has to be with respect to functional programme, functional and space requirement, work flow analysis, manpower requirement, instrument and equipment requirement. Team approach is necessary in the planning of hospitals in view of the multi-disciplinary nature of work in the field. The design of the hospitals must satisfy the professional requirements as well as needs and comfort of the patients. In this context the essential parameters to be taken into consideration at the time of planning of hospitals include round-the-clock availability of water, adequate arrangement for garbage disposal and uninterrupted supply of electricity. Provision of hydrants, fire alarms, fire extinguishers etc, is also necessary in consultation with the local fire authorities.

Parking

The problem of parking has assumed serious proportions in the existing hospitals in all metropolitan cities. Particularly in hospitals which were built 2-3 decades ago when automobile congestions were not known. As a result, whatever open space was available for gardening between the buildings, has been covered with hard core materials so that these can be used as parking lots. In view of this, it is obligatory to include this as an essential parameter by the planners and architects. Taking into account the recommendation of Indian Road Congress, efforts should be made to have at least one parking slot for every 10 beds.

To provide guidance on all these aspects for various categories of hospitals, work has been initiated by BIS for preparing Indian Standards on basic requirements for hospital planning for various categories of hospitals. Basic requirements for planning of up to 30 bedded hospitals, commonly known as community health centre, have already been published in the form of IS 12433 (Part 1) : 1988. The standard gives guidance on total area, site, planning, functional and space requirement, manpower requirement, instrument, equipment, building requirements etc. Relevant Indian standards on instruments, where ever available, have also been listed in the list of instruments. Community health centres, nursing homes and government hospitals would benefit from these standards.

The standard for 100 bedded hospitals is under finalisation. This standard comprises the following sections describing fundamental aspects of hospital planning namely :

Section - 1 Medical Programme
Section - 2 Functional Programme
Section - 3 Area Requirements
Section - 4 Work Flow
Section - 5 Manpower Requirements
Section - 6 Instruments and Equipment Requirements
Section - 7 Building Requirements

It is envisaged that above requirements will not only serve as guidelines for planning of 100 bedded hospitals but also will form the basis for development in the field to structure specific building standards for hospitals with more or less bed strength than 100 beds, with higher or lesser degree of specialisation. The, standards for 250, 500 and 750 bedded hospitals would also be prepared in due course of time.

In the present scenario of ever growing health needs, hospital planning has assumed more significance than ever. The fast pace of development of technology and rising demands on financial inputs have added new dimensions to the problem. To meet these challenges, every decision in hospital planning involves a series of choices which concern justification of the use of scarce funds, consideration of alternative health strategies and selection of the best from different modules of health care system. The efforts put in by BIS in this regard will help the hospital planners in creating proper infrastructure for hospital services at various levels, thereby providing essentials in medical care and achieving higher patient satisfaction and meaningful service to the community at large.

Quality System Certification

It has been established that ISO 9000 Certification is an effective tool for achieving customer / consumer satisfaction, for systematic working and also for training. Over a lakh ISO 9000 Certificates worldwide are a testimony to this

fact. The response of the Hospital sector is however, quite low and it is time that the hospitals also tap the benefits of this system by preparing for installation of the Quality Systems and obtain certification. The documented elaborate system of a hospital may result in improving efficiency ; standardised and well defined procedures for various functions ; easy retrievability of records; systematic and uniform handling and maintenance of medical equipment and instruments; controlled procedures; low failure in services and achieving the goal of ultimate patient care and satisfaction at nominal cost. It assumes added importance in view of the recent Supreme Court judgment regarding coverage of Doctors and Hospital Services within the ambit of Consumer Protection Act.

BIS is operating a Quality System Certification Scheme which has been accredited by the international body RVA (earlier known as RVC) Netherlands. BIS has granted about 190 Quality System Certificates (as per IS/ISO 9001, 9002. etc) and a good number of applications are at various stages of processing. Further details about ISO 9000 certification may be obtained from Director (Quality Systems). Bureau of Indian Standards, Manak Bhavan, 9 B.S. Zafar Marg, New Delhi 110002.

Annex VIII

QUALITY MANAGEMENT FOR HEALTH CARE SERVICES

A.K.Talwar

1. Quality In Service Industries

Service is a product in as much as it is bought by and affords satisfaction to customers. In today's competitive economy, the industry is consumer driven instead of being supplier-driven. It is the customer who is at the focus and all activities are to be oriented towards maximising customer satisfaction. Customer satisfaction can be measured in terms of quality of services rendered.

Millions of people buy various kinds of services directly from the seller daily (e.g. food, housing, electricity, transportation, communication). Furthermore, the buyer of services does not write specifications as in manufacturing. The buyer purchases in accordance with what laws, legislative acts, regulations and established procedures specify. Examples of such service industries are banks, insurance, real estate, public utilities, health services and communication. These characteristics distinguish service industries from those engaged in manufacturing.

When we evaluate the quality of service, it is essential that we persuade and train every single person involved to exude warmth and care. When you produce a soap, the person who is selling the soap is not important to quality, but, when you deliver a service, say medicare, the person delivering it becomes crucial. His human traits become a major part of quality, as users of that service perceive it.

2. Quality of Health and Medical Care Services

It is no surprise that the quality movement and its awareness is affecting the field of health and medical care services as well. In fact, there is a revolution coming in this field that would establish quality as the standard for excellence in

the health care industry. Health Care Services not only affect the highly valued well being of the society but also consume a significant part of country's wealth and employ a large number of people.

Health care services include a wide variety of quality aspects all of which are important. A lack of detailed information about any of these aspects means that we have not yet faced up to the need for quality control in numerous areas of vital interest to the customer. In case of medical services, the sellers are doctor, hospital, nursing home, clinic, etc, because they offer health services at stipulated prices. In case of government and other charity hospitals this price is paid from funds allotted to the hospital. The buyer wants acceptable quality services which must be commensurate with what he is paying the seller. Acceptable quality services not only include the quality of direct medical services such as diagnosis, medicines, surgery and treatments, but indirect operations such as administration, purchasing, stores, housekeeping etc, are also included whose costs are reflected in what the buyer pays. It may also include quality of performance that is directly connected and closely related to health care such as food, housing, safety, security, attitude of employees, and other factors which arise in the context of hospitals and nursing homes. A major factor of vital importance in health services is time. This may include consultation time, waiting time, service time, timing with regard to medicines, treatments and surgery, etc.

It must always be kept in mind that key person is the patient, the key characteristic is the health of the patient, and a related characteristic is the cost accrued to the patient. Regarding the security, the patient's personal property must be protected from being stolen. Hospitals where food is provided, the patients diet must be according to the patient's needs. The patient must not feel neglected at any stage. Necessary precautions, such as keeping abnormal patients (specially mental) separate from normal ones, patients suffering from infectious diseases be kept in protected area, etc, must be taken without exceptions.

The key word, however, is quality which is understood as customer satisfaction/fitness for use/conformance to specifications. However, the quality

of service should always be in line with the customer's needs and expections. Formally, the quality of hospital services rendered (based on the ISO definition of 'quality') may be defined as follows :

"Totality of characteristics of hospital service that bear on its ability to satisfy stated and implied needs of its patients"

3. Quality Management In Health Care Services

The health and medical care delivery system in our country are coming under increasing pressure due to increased utilisation as a result of population explosion, increased awareness among people, the literacy level having gone up; biomedical advancement resulting into the use of sophisticated and advanced technology in diagnoses and therapeutics; and constantly rising expectation levels of the buyers. Also the Government's commitment to the cause of the common consumer is amply reflected in the enactment of Consumer Protection Act (COPRA), 1986. With the introduction of COPRA, the need for evaluating the care being rendered in retrospect has further gained strength. Until now, the quality of health care being provided by the health care organisations could not be subjected to critical retrospective evaluation as there were no checks or controls on the care being rendered and there being no predetermined standards or guidelines in this area. Today, a common consumer expects some sort of assurance that the services rendered are of desired quality and are cost effective. Various functionaries, such as doctors, nursing and paramedical staff, hospital administrators, etc, should be held responsible for any failure in the system. There is a strong move to bring hospital services in the preview of consumer courts.

Keeping in view the changing environment and the needs of the community at large, it is felt that a system of quality control must be introduced in the health and medical care services which would ensure :

Safeguarding the interest of the buyer and the seller

Identifying the inadequacies in the system, including infrastructure (physical facilities, staff, equipments), and policy procedures.

Monitoring the optimum utilisation of resources viz-a-viz their maximum capacity output and cost effectiveness.

In contrast with the case of products, where the expected performance is often in terms of measurable attributes, the difficulty in case of services is that the consumer's needs and expectations are quite often abstract. Now withstanding this, a hospital keen to provide satisfactory service or to improve upon its present level of service, needs to have a mechanism to ascertain the patient's needs and requirements, even if they are imprecise or vague. This may be done by communication with the users of the service, customer survey, etc. Such attributes, which are important for the patient's needs and requirements, may be picked up. These attributes may be divided in two broad categories :

i) First relating to infrastructure, skills, procedures and systems, etc, which will ensure a satisfactory service at optimum cost. This is a prescription type of provision, adherence to which is expected to result in service of desired quality.

ii) The second part comprises of identification and quantification of attributes of quality which is of performance type of provision. Quantitative characteristics may include, waiting time, service delivery time, process time, bed occupancy rate, acquired infection rate, death rate, etc.

One of the major indicators of service quality is the feed-back received from patients. It is essential that such feed-back percolates down the line to every employee in the hospital. There may be number of systems to understand how the patients and their relatives feel, such as, suggestion schemes, complaint redressal system, group interviews, etc.

One of the major elements in the service area is the concept of consideration. Usually, price is a very important concept, in any industry. But in the services area, price has been replaced by the element of consideration. Consideration is price plus loss of dignity, waiting time, anxiety, etc. If a person coming to the hospital pays almost nothing, but had to suffer all above elements, he would certainly refuse to use the facility and endanger his life. Reducing consideration

is one of the major ways in which employees can enhance the quality of service. It is said that even if price is zero and consideration is high, no one will use that medical facility.

The latest concept in management is that of customer delight. In the 1980's it was thought sufficient to ensure customer satisfaction. It has now become essential to aspire for customer delight. Customer delight means that it is not enough, if a room is clean. It should smell great, be aesthetically pleasing, and have a beautiful arrangement. Customer delight means that a receptionist is not merely courteous, but is warm, empathic and well trained in counselling. It is not enough to have a 99% success rate in an open heart surgery, it is also important that a patient is trained in improving the quality of his life through a process of rehabilitation.

Since health service is mainly people - oriented, the prevention and reduction of human errors at all levels are of vital importance. This means that top priority must be given to human resource development. Some common examples of waste, rework, negligence and error in patient care in hospitals are :

- X-ray ordered but not utilised
- Prolonged stay before and after the operation
- Consultation indicated and not carried out
- Wrong label on samples
- Wrongly numbered reports
- Missing requisition, reports, etc
- Inferior quality of drugs used
- Delayed reports
- Prescriptions not explained
- Medicine prescribed but not given by the nurse
- Incorrect patient identification

4. Standardisation Effort by the Bureau of Indian Standards

While continuing all-out efforts to expand hospital services to cater to the needs of the common man, BIS also recognised the need felt for introducing quality management and quality assurance procedures in these services, so as to

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make them more effective, economical and accountable. This was particularly important for optimum utilisation of scarce resources available and managing them scientifically so that quality service is provided to patients on a continued basis. It is hoped that with these efforts of BIS, norms would be evolved and developed by which it would be possible to gauge the health and medical care services rendered, in retrospective evaluation with an objective to improve upon these services.

Primary health care has been adopted as the principal instrument of action for providing guidelines for planning and managing these services. Even though efforts have been made to improve the services, most of the hospitals up to 30-bedded in the country, particularly in the rural areas, lack in basic facilities leading to dissatisfaction of user community. In order to fulfil the imperative need to prepare guidelines and standards at national level for upgradation of the quality of hospital services and thus bringing about efficiency and effective patient care management, the Bureau of Indian Standards (BIS), which is the National Standards Body of the country, has prepared the following Indian standards through its Hospital and Medical Care Services Sectional (or Technical) Committee, MSD 8, which deals with standardisation activities relating to quality management and operational systems of health and medical care services :

IS 13808 Quality management for hospital services (Up to 30-bedded hospitals) - Guidelines

Part 1 : 1993	OPD and emergency services
Part 2 : 1993	Diagnostic and blood transfusion services
Part 3 : 1995	Wards, nursing services and operation theatre
Part 4 *	Hospital support services
Part 5 *	Hospital equipment management

* Parts 4 and 5 and in their advanced stages of formulation.

The above Indian Standards have been prepared by the Bureau with the expertise and guidance from various interests including individual experts, Government departments, professional bodies, medical institutions, hospital administrators and consumers. A brief outline of these standards is enclosed as Annex.

The purpose of these standards is to help in bringing-in consistency in day-to-day functioning of hospitals up to 30-bedded. This is necessary for improving the quality of patient care in hospital services. At present there is a gross inadequacy of standards/guidelines for hospital designing and planning of hospital services and these standards would not only bring consistency in hospital services but also improve their quality. This is particularly important, as the hospitals up to 30-bedded are mainly located in rural/semi-urban areas of the country and have been the victim of neglect. In this situation the present level of utilisation of such hospitals is quite inadequate resulting in waste of resources. There is an urgent need to strengthen these services and thus making them more effective and useful. The above mentioned Indian Standards will go a long way in fulfilling these objectives.

These standards are targeted for up to 30-bedded general hospitals, such as community health centres/subdistrict hospitals/intermediate hospitals and cover only a part of the quality management aspect of hospital services relating to infrastructure, skills, procedures and systems etc. This is a prescriptive type provision as mentioned earlier. Planning for infrastructure of the hospitals covering functional and space requirements, manpower requirements, instruments and equipment and building requirements, etc, are covered by another technical committee of BIS namely Hospital Planning Sectional Committee (MHD 18), under the Medical Equipment and Hospital Planning Division Council. In this context, reference may be made to IS 12433 (Part 1) : 1988 Basic requirements for hospital planning - Part 1 : 1988 up to 30-bedded hospital, prepared by MHD 18, which covers functional and space requirements including staffing instrument and equipment and building requirements.

Above mentioned prescription standards would now be utilised in developing standards for assurance of quality of services offered in a hospital up to 30-bedded. These performance standards would deal with identifying the quality parameters reflecting the needs of the customers (users, of these services) and establishing norms for evaluating these services with a view of improving service performance and customer satisfaction.Various elements to be covered in these standards would be based on IS/ISO 9000 series of standards on

quality systems, in particular ISO 9004-2. The key concepts of phase I revision (already completed) and phase II revision (in progress) of IS/ISO 9000 series of standards would be appropriately reflected in performance and quality assurance standards being prepared by MSD 08. The tentative Title and Scope of these standards will be in line with that given at the end of the Annex enclosed.

5. Conclusion

Thus it is quite clear that the need of the hour is to provide hospital and medical care services of desired quality to the patients. This assumes special significance in the context of primary health centres in our country. For achieving it, following action plan needs to be followed wholeheartedly :

a) The dissemination of the knowledge on Indian standards published/to be published mentioned above and their extensive implementation by all concerned.

b) Evolving and implementing Quality Management System by hospital/health authorities based on Quality System Standards in IS/ISO 9000 series of standards with the guidance available in Indian Standards and other relevant documents on hospitals and medical care services.

C) Identification of parameters for Quality assurance to the users of hospital and medical care services and developing a system for evaluating them. As mentioned above, an Indian standard providing guidelines on this subject is under preparation. Till then, hospitals can evolve their own norms based on their experience, customer surveys, and provisions of ISO 9004-2 : 1991.

d) Taking advantage of Quality Systems Certification Scheme according to IS/ISO 9001, 9002 or 9003, which would provide third-party assurance to the customers on the implementation of relevant ISO 9000 standards.

Quality System Standards provide a good tool for building in, maintaining and improving the hospital and medical care service to the customers (patients).

They help suppliers (hospital management / health authorities) to manage quality of services in a more effective manner leading to customer satisfaction / welfare / delight, thereby safeguarding there interests and that of society, at large.

One of the salient features of quality systems, standards is that three quality assurance models represented by IS /ISO 9001, 9002, or 9003 are amenable to quality system certification. BIS has been authorised by Govt. of India under an act of parliament to operate such certification scheme. The operation of the scheme is in harmony with the international practices as enunciated in relevant ISO guide and meets the criteria of European community as stipulated in EN - 45012. The accreditation of BIS scheme, which covers manufacturing as well as service sector, by Raad Voor de Certificate (RVC), Netherlands is a testimony to it. Thus hospitals and medical care services are also covered under the scheme.

ANNEX

BRIEF OUTLINE OF THE INDIAN STANDARDS ON QUALITY MANAGEMENT FOR HOSPITAL SERVICES

IS 13808 (PART 1):1993 QUALITY MANAGEMENT FOR HOSPITAL SERVICES (IN HOSPITALS UPTO 30-BEDDED)- GUIDELINES- PART 1: OUT-PATIENT DEPARTMENT (OPD) AND EMERGENCY SERVICES

Until now, quality concepts were applied in the hospital environment in fragments. The medical staff was concerned with the quality of its actions to control and monitor only the clinical and nursing aspects of care. Other services in the hospital , such as, supportive and diagnostic services, have their own quality assurance programmes. But what is lacking is a integrated approach. The infrastructure must facilitate high-quality performance from every sub-system within the hospital for effective and efficient patient care. Smooth functioning of the supportive and utility systems will facilitate high quality of technical and professional care leading to improved patient satisfaction.

The purpose of this standard is to provide guidelines for evolving well-planned and systematic procedures which would result in quality health care to the patients relating to OPD and emergency services in a 30-bedded hospital .

SCOPE: This standard lays down guidelines for quality management procedures for OPD and emergency services offered in up to 30-bedded general hospitals.

IS13808 (part 2):1993 QUALITY MANAGEMENT FOR HOSPITAL SERVICES (IN HOSPITALS UPTO 30-BEDDED)- GUIDELINES- PART 2 : DIAGNOSTIC AND BLOOD TRANSFUSION SERVICES

Most of up to 30-bedded hospitals in the country, particularly in rural areas, lack in the basic facilities leading to dissatisfaction to user community. Therefore, there is an imperative need to set up guidelines and standards for up gradation of diagnostic and blood transfusion services in the existing hospitals up to 30-bedded and also for starting the new ones.

This standard intends to provide guidance for evolving a well planned quality assurance programme which would result in quality health care to the patients in relation to diagnostic and blood transfusion services in up to 30-bedded hospital.

SCOPE : This standard lays down guidelines for quality management procedures for diagnostic and blood transfusion services offered in general

hospitals up to 30-bedded with reference to

a) Pathological Services - The system of collection of blood, urine, and other body fluid samples and their processing.
b) Imaging Services - The system of imaging of patients by X-ray and ultra sound.
c) ECG Services
d) Blood Transfusion Services

IS13808 (part 3): 1995 QUALITY MANAGEMENT FOR HOSPITAL SERVICES (IN HOSPITALS UPTO 30-BEDDED): PART 3 : WARDS, NURSING SERVICES AND OPERATION THEATRE

There is imperative need to set up some guidelines and standards for upgradation (both qualitative and quantitative) of in-patient services with a view to control the hospital acquired infection, minimise nurse fatigue, provide basic amenities to the in-patients and minimise the bottle-necks in the day to day functioning of the hospital and also to bring about efficiency and effective patient care management.

SCOPE : This standard lays down guidelines for quality management procedures for a) Wards

b) Nursing Services
c) Operation Theatre
d) Labour Room

in up to 30-bedded general hospital.

IS 13808 (PART 4):199_ QUALITY MANAGEMENT FOR HOSPITAL SERVICES (IN HOSPITALS UPTO 30-BEDDED)- GUIDELINES : PART 4 HOSPITAL SUPPORT SERVICES

Quality management guidelines for hospital support services for up to thirty bedded general hospital, aims at defining the various activities for quality product or services at minimal cost. This involves organisation and utilisation of all the members of the team and their functioning by means of monitoring, improving and upgrading the process. Taking the similar and allied functions together, hospital support service activities for up to thirty bedded hospital may be grouped into various sub-units, such as, Hospital stores, CSSD, Laundry, Kitchen, Housekeeping, Maintenance, etc.

SCOPE : This standard lays down guidelines for quality management system for hospital support services offered in general hospitals up to 30-bedded with reference to

a) Hospital supply system
b) Central Sterile and Supply Department (CSSD)
c) Hospital laundry and linen services
d) Hospital dietary service
e) Housekeeping

IS 13808 (PART 5):199_ QUALITY MANAGEMENT FOR HOSPITAL SERVICES (IN HOSPITALS UPTO 30-BEDDED) - GUIDELINES : PART 5 HOSPITAL EQUIPMENT MANAGEMENT

There is a large variety and diversity of equipments in a hospital. The nature and type of equipments vary in different hospitals depending upon the competencies and size of the hospital. To illustrate a few areas, the range varies from a simple B.P. Apparatus to highly sophisticated diagnostic and therapeutic gadgets, laboratory equipments, imaging equipments, anaesthesia and O.T. equipments, etc.

In order to provide and establish efficient equipment maintenance services in hospitals, it is important that a written plan or a guideline be developed to monitor these services, right from procurement up to the disposal of equipments, especially when these equipments are based on sophisticated and high cost technology involving huge funds from constrained resources. Further, the plan would endeavour to incorporate facilities for training in equipment management including equipment audit, maintenance and repairs for technicians and other paramedical personnel which form a vital link in the quality management system with respect to hospital equipment.

SCOPE : This standard prescribes guidelines for establishing a system for hospital equipment management in a general hospital up to 30-bedded, which include :

a) Procurement; utilisation; equipment audit; maintenance and repairs; condemnation and disposal practices;

b) training of technicians and other paramedical personnel.

QUALITY ASSURANCE STANDARD (Under Preparation)

TITLE : Quality assurance requirements for hospital services for hospitals up to 30-bedded)

SCOPE : This standard lays down performance requirements (qualitative and quantitative) reflecting the needs of the users of hospital services and a system for evaluating these services for hospitals up to 30-bedded.

PROPOSED DRAFT ON QUALITY ASSURANCE IN HOSPITAL SERVICES FOR 30-BEDDED HOSPITALS - GUIDELINES: PART 1 PERFORMANCE REQUIREMENTS

SALIENT FEATURES

1 COMUNICATION WITH CUSTOMERS

2 IDENTIFYING RELEVANT INFORMATION AND DATA

3 PERFORMANCE REQUIREMENTS

3.1 GENERAL PERFORMANCE REQUIREMENTS

a) RECEPTION AND REGISTRATION
- — COURTEOUS RESPONSE
- — INFORMATION PROVIDED
- — GUIDANCE NEEDED

b) STAFF SERVICE
- — COURTESY
- — COMFORT
- — PROMPTNESS

c) HOUSEKEEPING AND SANITATION
- — CLEANLINESS AND HYGIENE
- — SAFE AND EFFECTIVE GARBAGE DISPOSAL AFTER BEING SEGREGATED INTO INFECTIVE AND NON-INFECTIVE, THROUGH INCINERATOR (OIL FIRED, ELECTRICAL, BRICK OR OTHERS)
- — HORTICULTURE AND LANDSCAPING (AVAILABILITY OF THESE SERVICES TO BE ENSURED)
- — LINEN AND LAUNDARY SERVICES

d) MEDICAL FACILITIES AVAILABLE
- — X-RAY
- — PATHOLOGICAL
- — SONOGRAPHY (OPTIONAL)
- — ESSENTIAL DRUGS
- — OTHERS

e) OTHER FACILITIES AVAILABLE
- CANTEEN
- LAUNDARY
- KITCHEN
- DRINKING WATER
- CHEMIST SHOP
- WAITING SPACE FOR PATIENT'S RELATIVES
- PUBLIC RELATION AND SOCIAL WORK

f) FOLLOW-UP CARE

g) QUANTITATIVE REQUIREMENTS
- BEDOCCUPANCY RATE 80-90%
- AVERAGE LENGTH OF STAY 3-5 DAYS
- NET DEATH RATE PER MONTH 3 % MAX
- ACQUIRED INFECTION RATE 10% MAX
- NUMBER OF ADMISSIONS, DISCHARGES AND LAMAs PER MONTH

3.2 PARAMETERS IN CASUALTY/OPD

3.3 PARAMETERS FOR IN-PATIENTS

3.4 PARAMETERS IN DIAGNOSTIC SERVICES

3.5 PARAMETERS IN SUPPORT SERVICES

APPLICATION OF STATISTICAL METHODS

Indian Standards on Quality Management for Hospital Services

IS 13808 — **Quality Management for Hospital Services (30-Bedded Hospitals) - Guidelines**

Part 1:1993 — **OPD and Emergency Services**

Scope : This standard lays down quidelines for quality management procedures for OPD and emergency services offered in 30-bedded general hospitals.

Part 2:1993 — **Diagnostic and Blood Transfusion Services**

Scope : This standard lays down guidelines for quality management procedures for diagnostic and blood transfusion services offered in 30-bedded general hospitals with reference to

a) Pathological Services - The system of collection of blood, urine, and other body fluid samples and their processing.

b) Imaging Services - The system of imaging of patients by X-ray and Ultrasound.

c) ECG Services

d) Blood Transfusion Services.

Part 3:1993 — **Wards, Nursing Services and Operation Theatre**

Scope : This standard lays down guidelines for quality management procedures for

a) Wards

b) Nursing services

c) Operation theatre

d) Labour room

in a 30-bedded general hospital.

Part 4:1996 **Hospital Support Services**

Scope : This standard lays down guidelines for quality management system for hospital support services offered in 30-bedded general hospitals with reference to

a) Hospital supply system

b) Central Sterile and Supply Department (CSSD)

c) Hospital laundary and linen services

d) Hospital dietary service

e) Housekeeping

Part 5:1996 **Hospital Equipment Management**

Scope : This standard prescribes guidelines for establishing a system for hospital equipment management in a 30-bedded general hospital, which include :

a) procurement; utilization; equipment audit; maintenance and repairs; condemnation and disposal practices;

b) training of technicians and other paramedical personnel.

IS 13808 (Part 3) : 1995
Quality Management for Hospital Services (30 Bedded hospitals) - Guidelines Part 3 Wards, Nursing Services Operation Theate and Labour Room

1 PLANNING

1.1 Physical Facilities

— Location and Building Requirements
— Functional and Space Requirements
— Staff, Instruments and Equipment Requirements

Reference may be made to different clauses of IS 12433 (Part 1) : 1988 Basic Requirments for Hospital Planning, Part 1 - 30 bedded hospitals

1.2 Expected Workload

— Not more than 30 patients at any given time
— To achieve this and provide desired quality service to patients, optimum utilization of wards and nursing services is essential

In Operation Theatre and Labour Room, 75 major/minor obstetical and surgical procedures are expected in a month.

2 ORGANIZATIONAL STRUCTURE

3 FUNCTIONAL MANAGEMENT

3.1 Timings of Wards and O.T.

3.2 Functional activities

— Ward and Nursing Service
— O.T. (Basic facilities, operational procedures, precautionary measures and patient flow)
— Labour Room

4 PROCEDURE MANUAL

4.1 Personnel Development

4.2 Maintenance of Equipment and Materials Management

— Maintenance of Equipment
— Storage and Handling of materials

5 PERFORMANCE EVALUATION

Annex IX

QUALITY UPGRADATION IN PRIMARY HEALTH CARE

Dr. Ashok Sahni and
Dr. Sudha Xirasagar

I Introduction

The Government of India is committed to the goal of Health for All by 2000 to be achieved through primary health care. Primary health care is the essential health care, made universally available to individuals, families and communities, available and accessible, for a certain basic level of health, at a cost the community and country can afford. Primary health care in the Indian contrast, includes curative care for minor ailments, control of communicable diseases, preventive and promotive health programmes for mother and child health, safe water and sanitation, family planning services and health education.

To provide primary heal;th care to all, the Government has established a network of rural health infrastructure widely dispersed throughout the country, which includes approximately 1,30,219 sub centres and 22,441 PHCs, in addition to a network of referral hospitals. Each sub centre on an average, caters to approximately 5,000 rural population, and each PHC covers approximately 30,000 rural population, in line with the goals set up in the Sixth and Seventh Five Year Plans. So far, rightly, the emphasis of the Central and State Government has been on quantity of health infrastructure. To achieve results, the emphasis now has to be on quality.

II Quality Assurance In Primary Health Care - Issues

The issues pertaining to two major aspects :

A) the content of Quality Assurance (QA) design and implementation

B) The context of QA implementation.

A) the content of Quality Assurance (QA) - The Issues

1. Quality refers to conformance to standards or requirements.

2. Quality Assurance is not a one time effort. It is a constant process.

3. Quality measurement and control in Primary Health Care is faced with the following issues.

a) As with all services, quality, definition in health care has eluded easy definition due to the four major attributes of a service, as opposed to a industrial product, the attributes being intangibility, variability, perishability, and inseparability (from the service giver). Therefore standardisation and quality monitoring has not been streamlined in the service sector.

b) In addition, health care service has an additional dimension of unpredictability of outcome in absolute terms, due to biological variation in response. Therefore a particular service outcome in a given case cannot be considered as representative of quality. Eg anaesthetic death or post operative infection.

c) Primary health care has two additional attributes posing problems for standardisation and QA work.
   i) Remote location and widespread field of operations
   ii) Free of cost to the receiver, hence a primary source of feedback does not operate.

B) Principles of QA evolved for the Health Care Sector

Keeping in view the specific issues faced in health service standardisation, the following guiding principles of QA in health care have been evolved by the WHO :

1. Professional performance (technical quality)

2. Health Care Outcome
3. Efficiency of Resource use
4. Risk Management, and
5. Patient Satisfaction

C) Fundamental Requirements to be conformed to in PHC

Keeping in view the above guidelines for QA in health care, and the "requirements" to be satisfied by primary health care services, the parameters for quality planning and control can be evolved. "Requirements" of PHC to be conformed to, are as follows :

"Requirements" of Primary Health Care Services Implications
- Essential health services -> Basic Curative, Preventive & Promotive
- Made universally available to all -> universal coverage
- Acceptable -> Patient satisfaction
- To achieve a basic level of health -> outcome of HFA to be achieved.

D) The proposed parameters for Quality Assurance

How do we measure conformance to these requirements?
According to Dr. Kirsten Staehr Johansen Head of Quality of Care Technologies in WHO, one of the means to ensure systems to monitor and improve quality of care. Basic cost effective tools of QA can be,

a) Surveillance and feedback to provide performance data

b) Use of computerised information systems to measure performance, develop indices of satisfactory performance, refine upon these indices, identify probable sources of recurring problems, and evaluate corrective actions.

For surveillance and feedback, parameters have to be defined, keeping in view

the requirements of primary health care, and the QA principles for the health care sector. Accordingly, some of the broad sets of QA parameters proposed to be measured towards upgrading quality of primary health care are the following:

a) Coverage and outreach of health programmes - service indicators, through feedback data from out patients or selected subsets of out-patients.

Proportion of eligible persons covered for a service - measure of professional performance

- Fever cases covered for blood smear
- Fever cases coming repeatedly for treatment without smear taken
- Mothers provided safe delivery services in taken the last delivery
- Mothers provided antenatal care, TT, Iron and Folic Acid etc
- Under five children provided immunisation, IFA, Vitamin A solution

b) Morbidity associated with lack of coverage eg : neonatal / maternal death ; respiratory infections / diarrhoea incidence associated with lack of Vitamin A coverage ; Malaria cases ; Mental Retardation, umbilical cord infections in neonates; puerperal sepsis cases.

c) Incidence of complications or undesired outcome associated with provision of a service - eg : Post tubectomy infection; pregnancy after tubectomy, injection abscess; tubectomy death; vaccination death; post vaccinations measles, polio.

d) Review of all deaths in the area in relation to possible association with primary health care services - provision or omission.

e) Clientele satisfaction with services :

- Availability of medical & auxiliary staff services regularly and at the time of need.
- Waiting time, relief from symptoms, perceptions about courtesy and culture - specific expectations of patients from care givers.

III Context of QA - The Issues

A Problems and issues to implementation of QA.

While at a cognitive level it is a relatively simple matter to identify parameters of quality designs systems and formats for data collection, major issues related to implementation of QA need to be addressed.

a) In health care, as opposed to the manufacturing sector, service providers normally perform as professionally autonomous entities, and professional paranoia prevails regarding any attempt to standardise services or monitor performance against predetermined standards.

b) Given the low morale of primary health care staff due to low job context factors, it is difficult to expect enthusiastic response to quality assurance, which could be perceived as one more burden on an already over loaded PHC system.

c) On the other hand, given the geographic territory of operations of primary health care, the success of surveillance and feedback depends very much on the enthusiasm and participation of the same primary health care staff, who are also the care providers.

Therefore the context of implementation of QA is equally important, as the content of QA activities.

IV. Approaches to creating a positive context for QA implementation

a) The top leadership of the health system at the State level should be fully convinced and committed to Quality upgradation.

b) In turn the State level should take steps to create awareness and

commitment to quality of Primary health care among District Health Officers.

c) Job context and career growth opportunities of primary health centre doctors should be improved towards improving their morale.

d) District Health Officers in turn should be responsible to create a culture of quality - consciousness among PHC doctors and they in turn among their staff.

e) As a policy, at all levels quality related surveillance and feedback data should be used strictly only for problem solving for service improvement, and not for fault - finding and punishment. This should be clearly communicated to all levels, to ensure a free and fair reporting which is the basis of QA.

f) QA activities should be integrated in to the routine health sector activities as follows :

Step I QA Data collection on separate form to be done as a routine at Registration of out-patients desk in all PHCs Taluk Hospitals and District Hospitals.

Step II Report compilation on daily, weekly or monthly basis to be done routinely, on par with daily and monthly statistics compilation.

Step III Reporting to the next level of Information - handling system to be done weekly and monthly, depending on nature of information (PHC to District level, District to State, State to National level).

Step IV Appraisal of findings and problem solving to be integrated into the weekly and monthly meetings in case of Primary Health Centres, and monthly meetings at District and State level.

Step V Data analysis at District, State and National levels, through computerised information system, should constantly aim to refine the parameters of Quality, identification of problems and their causes, define priorities for action, and devise parameters for QA in newer dimensions (eg. Efficiency of resource use dimension), etc.

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